IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC., Plaintiff, v. DEY, L.P., and DEY, INC., Defendants.	C.A. No. 06-113 (JJF) C.A. No. 06-604 (JJF) CONSOLIDATED
SEPRACOR INC., Plaintiff, v. BARR LABORATORIES, INC., Defendant.	C.A. No. 07-438 (JJF)

SEPRACOR'S ANSWERING CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

Barr and Dey cannot even agree on a narrowing construction of Sepracor's patent claims. They seem to agree, however, that this Court should abandon well-established claim construction canons in favor of known claim construction missteps, such as reading extraneous limitations into claims and considering validity arguments during claim construction. It is therefore no surprise that Barr's and Dey's flawed approach to claim construction leads to illogical results. For example, under both Barr's and Dey's constructions, the claim term "side effects" would exclude airway hyperreactivity -- a side effect on which Sepracor and the Patent Office specifically relied in supporting and allowing the claims that are directed to methods for reducing "side effects." Similarly, under Dey's construction, the claim term "side effects" would exclude many, if not all, of the side effects specifically identified in the patent specification because of Dey's unsupported and extraneous requirement that this term be limited to "beta-adrenergic side effects" (whatever that means) and teratogenic side effects "caused ***directly*** by the S(+) isomer of racemic albuterol" (whatever that means).[1]

In addition, Dey's constructions of the terms that Barr did not dispute in its opening claim construction brief, *e.g.*, "chronic administration," seek to redefine the plain and ordinary meaning of unambiguous claim terms.[2]

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[1] Emphasis in the quoted material is added unless otherwise noted.

[2] The only claim term that Barr addressed in its opening brief is the "side effects" limitation that is found in many of the asserted patent claims. Barr chose not to address any other claim terms even though it was aware of Sepracor's proposed claim constructions since February 11, 2008 -- the date Sepracor provided full and complete responses to Barr's interrogatories regarding claim construction. After the filing of opening *Markman* briefs, Barr announced that it would address in its answering *Markman* brief claim terms that it did not address in its opening brief. [Exh. 17.] Sepracor respectfully requests that the Court exclude any argument on new claim terms. *See Advanced Medical Optics, Inc. v. Alcon Inc.*, 361 F. Supp. 2d 404, 418 (D. Del. 2005) (refusing to allow argument presented for the first time in a reply brief regarding

(Continued . . .)

Sepracor's constructions, on the other hand, derive from the plain language of the claims and are firmly grounded on well-established claim construction principles. Sepracor does not ask the Court to read extraneous limitations into the Sepracor patents or to delve into an improper validity analysis during claim construction.

ARGUMENT

A. The Proper Construction Of The "Side Effects" Limitation

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects are those associated with acute/chronic administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	The side effects are limited to beta-adrenergic side effects and teratogenic effects caused directly by the S(+) isomer of racemic albuterol.[3]	The side effects are limited to the side effects specifically identified in the patent specification at column 3, lines 28-31, 33-35.

Barr argues that the claim term "side effects" should be limited to only those side effects specifically identified in the patent specification. Barr's first misstep is that it ignores the

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(. . . continued)
summary judgment based on D. Del. LR 7.1.3(c)(2), which states "[t]he party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief."); *Inline Connection Corp. v. AOL Time Warner Inc.*, 347 F. Supp. 2d 56, 59 n.16 (D. Del. 2004) (granting plaintiff's motion for reconsideration - a procedure not even recognized in this district - because defendants argued for a new definition for a claim term for the first time in its responsive brief, which made the Court "sympathetic to [Plaintiff's] complaint that at 'the eleventh hour [defendants] chang[ed] a [proposed] definition.'"); *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 434 F. Supp. 2d 308, 313-14 (D. Del. 2006) (granting Plaintiff's motion to strike certain contentions in Defendant's reply brief because those contentions were not offered in opening brief). If, this Court nonetheless permits Barr to present arguments regarding terms it did not address in its opening brief, Sepracor reserves the right to seek leave to file a reply brief to respond to them.

[3] Dey originally construed the "side effects" limitation to mean the side effects specifically disclosed in the '755 patent at column 3, lines 28-35. [*See* D.I. 269, Exh. 13, Dey's Response to Sepracor Interrogatory No. 1 at 3.] Now, in these *Markman* proceedings, Dey adds further limitations that the term "side effects" must be beta-adrenergic side effects caused directly by the S(+) isomer of racemic albuterol.

plain language of the claims and begins its analysis with the patent specification. *See Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204 (Fed. Cir. 2002), *cert. denied*, 538 U.S. 1058 (2003), *restricted on other grounds by Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*) ("Consulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims.")

Using Claim 1 of the '755 patent as an example, the plain language of the claim begins with the well-known term "side effects." There is no ambiguity about this claim term. It is undisputable that the plain and ordinary meaning of "side effects," as would be apparent not only to one of ordinary skill, but to a lay person as well, is "[a] result of a drug…in addition to…the desired therapeutic effect." [*See, for example*, Exh. 18, Stedman's Medical Dictionary 25th Ed. at 1416.][4] No further construction of this claim term is required. *See Phillips*, 415 F.3d at 1314 ("the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of widely accepted meaning of commonly understood words.")

To the extent that the term "side effects" is further modified in Claim 1 of the '755 patent, it is modified by language that also is plain to one of ordinary skill in the art: "side effects ***associated with chronic administration of racemic albuterol***." [Exh. 1, '755 patent, Col. 4:7-8.] Thus, applying the common definition of "side effects," one of ordinary skill in the art would understand the claim term "side effects associated with chronic administration of racemic

[4] "Exh. __" refers to exhibits attached to the April 10, 2008 (D.I. 269) and May 1, 2008 Declarations of Preston K. Ratliff II.

albuterol" to simply refer to any side effect (or, result of a drug in addition to the desired therapeutic effect) associated with chronic administration of racemic albuterol. By adopting the plain meaning, there is no need or justification for further limiting or attempting to define some subset of side effects that is covered by this broad claim term. If treatment in accordance with Sepracor's patented methods results in any reduction of any side effect associated with chronic administration of racemic albuterol, then it meets the plain meaning of this claim term, whether that side effect is "caused ***directly*** by S(+)" (whatever that means), whether it is "beta-adrenergic" (whatever that means), or whether it is specifically disclosed in the clearly ***illustrative*** list of side effects set forth in the patent specification.

Barr, however, asks this Court to read into the claims limitations from the patent specification. In its brief, Barr argues that the patent specification "defines" "side effects" as related to the central nervous system, the heart, and teratogenic effects. [D.I. 270 at 11.] This is incorrect. As Sepracor explained in its opening brief, the patent specification uses terms of illustration, such as "for example," "such as," and "include." [D.I. 268 at 10-11.] Therefore, the claims are not limited to any specific example of side effects specifically identified in the patent specification. *See Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1150-51 (Fed. Cir. 2003) (refusing to limit the term "floral holding material" to floral foam or soil disclosed as a preferred embodiment because "[t]he written description makes quite clear that the open-ended examples of 'floral holding material' are merely illustrative; that is, they do not exhaustively delineate the 'floral holding material' that is clearly defined in the claims."); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions

of manifest exclusion or restriction.'" (*quoting Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

Barr also argues that the patent claims should be limited to the examples of side effects specifically identified in the patent specification because allegedly only those side effects were known to the inventors at the time of filing the patent. [D.I. 270 at 11.] In support of its argument, Barr cites the deposition testimony of one of the inventors, Dr. James Young. [D.I. 270 at 11.] This extrinsic evidence cannot change the unambiguous plain meaning of the claim term. *See Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992) ("The litigation-induced pronouncements of [the inventor], coming nearly at the end of the term of his patent, have no effect on what the words of that document in fact do convey and have conveyed during its term to the public.") (quoting *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984)); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.")[5]

Moreover, the Federal Circuit has made clear that claim terms can embrace later arising technology, whether or not that technology was known at the time of the invention. *See SuperGuide* Corp. *v. DirecTV Enterprises*, 358 F.3d 870, 881 (Fed. Cir. 2004); *Marsh-McBirney, Inc. v. Montedoro-Whitney Corp.*, 882 F.2d 498, 504 (Fed. Cir. 1989), *vacated on other grounds*, 498 U.S. 1061 (1991), *reinstated in relevant part*, 939 F.2d 969 (Fed. Cir. 1991). In

[5] The deposition testimony cited by Barr does not support its argument. Dr. Young, one of two inventors, guessed in his deposition as to which side effects were specifically identified in the patent specification: "I ***think*** our intention was to enumerate them all, all that we were aware of." [D.I. 271, Exh. 21 at p. 193.] This testimony merely stands for the obvious, namely, that based on his memory 17 years after filing the patents-in-suit, one of the inventors "thinks" the specification was "intended" to list the side effects the inventors were then aware of. This testimony provides no aid to the relevant question here, *i.e.*, how the claim term "side effects" should be construed as a matter of law.

SuperGuide, the district court limited the claim term "regularly received television signal" to analog television signals based on the state of the art at the time of invention. 358 F.3d at 876. The Federal Circuit reversed, determining that the claim language did not limit the disputed term to any "particular type of technology or specify a particular type of signal format, such as analog or digital." *Id.* at 878. It held that "[t]he form of the television signal is irrelevant; it could be an analog signal, a digital signal, some combination of the two, ***or another format***." *Id.* at 881. In *Marsh-McBirney*, the district court found noninfringement because the defendant used a new type of probe. 882 F.2d at 504. The Federal Circuit reversed, holding that "[a]dvances subsequent to the patent may still infringe" and that "whether the velocity sensors are electromagnetic or acoustic, bi-directional or not, they are 'probes' encompassed by" the claim term. *Id. See also Bd. of Trustees of Stanford Univ. v. Roche Molecular Sys., Inc.*, 528 F. Supp. 2d 967, 980 (N.D. Cal. 2007) (refusing to limit the claim term "an antiretroviral agent" to those antiretroviral agents known at the time of the invention and specifically holding that the term "an antiretroviral agent" refers to a category that "would only expand over time").

Contrary to Barr's argument, the cases it cites - - *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347 (Fed. Cir. 2000) and *Medtronic Navigation, Inc. v. BrainLab Medizinische Computersysteme GmbH*, 222 F. App'x 952, 956 (Fed. Cir. 2007) - - do not support its position. [D.I. 270 at 16.] In *Schering*, the patentee isolated and deposited in the Patent Office a type of DNA identified in his patent claims as "leukocyte interferon." *Schering* at 1352-1354. The patentee later amended his patent claims to substitute "IFN-α" for the term "leukocyte interferon" because of a change in nomenclature in the relevant art. *Id.* at 1352-1353 ("[The inventor explained] that the leukocyte interferon he had isolated and produced now has a new scientific name.") Many years later, scientists learned that the patentee had actually discovered a

subtype of "IFN-α," called "IFN-α-1." *Id.* at 1351. The Federal Circuit refused to construe the patentee's claims to cover any subtype of "IFN-α" other than "IFN-α-1" -- the sub-type that the patentee isolated and deposited in the Patent Office. *Id.* at 1353-1354 ("[T]he patentee expressly limited the meaning of the term 'IFN-α' to define the leukocyte interferon [the inventor] described in his original application."). In the present case, the intrinsic record makes plain that the inventors were not limiting the "side effects" term to any particular side effect.

The non-precedential *Medtronic* case involved an ambiguous claim term -- the term "establishing the spatial relationship." 222 F. App'x at 956. The Court resolved the ambiguity by rejecting a construction that, in the Court's view, included non-enabled subject matter. *Id*. at 956; *see also Phillips*, 415 F.3d at 1327 (validity construction should be used as a last resort, not a first principle: "we have limited the maxim [that claims are to be construed to preserve validity] to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'" (*quoting Liebel-Flarsheim*, 358 F.3d at 911)). Neither Barr nor Dey argue that Sepracor's construction of "side effects" is not enabled. Indeed, as discussed above, Sepracor expressly relied on a side effect not specifically identified in the patent specification to support the patentability of its claims.

Further, as explained in Sepracor's opening brief, Barr's construction would exclude a demonstrated "side effect" (airway hyperreactivity) on which Sepracor specifically relied in demonstrating the claimed reduction in "side effects," and which the Patent Office recognized in granting the patents. [D.I. 268 at 11.] It is completely illogical to exclude a specific "side effect" that was important to the allowance of the claims, as both Dey and Barr would do. Indeed, both Barr and Dey recognize the important role of the prosecution history in construing the claims of the patent (D.I. 270 at 6; D.I. 264 at 19), but never come to terms with

the issue of why this Court should ignore the very type of side effect that led to allowance of the claims.

Barr and Dey claim that side effects like airway hyperreactivity should not count because Sepracor acknowledged that this side effect was not specifically disclosed in the illustrative list of side effects in the patent specification. [D.I. 270 at 15-16; D.I. 264 at 23.][6] This makes no sense. The fact that a particular side effect was relied on by the Patent Office and Sepracor during prosecution even though it was not expressly disclosed in the patent specification, strongly supports that the "side effects" term should not be limited to the illustrative list in the specification. It further proves that both Sepracor and the Patent Office accepted this conclusion.

Further, in an effort to force its flawed claim construction, Barr finds itself in the unique position of advocating for the validity of the very claims it is trying to invalidate. Barr argues that Sepracor's proposed construction of the side effects limitation "would violate the definiteness and written description requirements of 35 U.S.C. § 112" and therefore must be improper. [D.I. 270 at 6.] First, it is telling that Dey apparently does not agree with Barr on this point. Indeed, Barr's approach confuses validity and claim construction, improperly putting "the validity cart before the claim construction horse." *See Landers v. Sideways, LLC*, 142 Fed. App'x 462, 468 (Fed. Cir. 2005). It is well-settled law that it is rarely, if ever appropriate, to construe a claim term by consideration of validity issues. *See Markman v. Westview*

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[6] Barr's citation to a non-inventor patent declarant's statement that hyperreactivity was a "previously undisclosed advantage" is misleading. (D.I. 270 at 16.) The patent declarant was explaining that hyperreactivity was not previously disclosed ***in the prior art***. It had nothing to do with what was disclosed in the patent specification.

Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) (matters which address claim validity are not relevant to claim construction and interpretation); *Takata Corp. v. AlliedSignal, Inc.*, No. 98-94, 1999 WL 787896, at *8 n.15 (D. Del. Aug. 19, 1999) ("The Federal Circuit Court of Appeals has consistently rejected the consideration of such [invalidity] argument[s] at the claim construction stage and continues to draw a line between claim construction issues and issues of infringement and invalidity…. The Court will not consider the merits of any such arguments while engaging in claim construction."); *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("Ambiguity, undue breadth, vagueness, and triviality are matters which go to claim validity for failure to comply with 35 U.S.C. § 112–¶ 2, not to interpretation or construction."); *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, No. 02-148, 2003 WL 124149 at *1 n.1 (D. Del. Jan. 13, 2003) (refusing to address the defendants' indefiniteness argument during the *Markman* stage of the proceedings).

Indeed, there is nothing indefinite about the term "side effects." As stated above, it has a well known meaning in the medical (if not the lay) community. It is simply an effect in addition to the desired therapeutic effect. [Exh. 18 at 1416.] It is not necessary to specifically delineate every possible side effect covered by the patent claims in this proceeding in order to give some meaning to this well known term. At trial, it will be a factual matter (not appropriate for this claim construction proceeding) to determine whether, in fact, Barr's and Dey's products provide a reduction of side effects associated with administration of racemic albuterol.

Moreover, if indefiniteness were a concern in this proceeding, that would counsel even more strongly against adopting Dey's proposed construction of the "side effects" limitation. Dey argues for a construction of "side effects" that limits the term, in relevant part, to beta-adrenergic side effects caused directly by the S(+) isomer of racemic albuterol. This

construction is impermissibly vague on two counts. First, it begs the question: what is a "beta-adrenergic" side effect? Dey offers no definition of this term and none is given in the intrinsic record. Dey asserts, without any support whatsoever, that airway hyperreactivity, *i.e.*, the very side effect relied on to secure allowance of Sepracor's patent claims, is not "beta-adrenergic," but never explains why that is the case. [D.I. 264 at 23-24.]

Still further, Dey also asserts that "beta-adrenergic side effects" are caused by the R(-) isomer and not by the S(+) isomer of racemic albuterol: "[C]ontrary to the inventors' expectations and as disclosed in the prior art, it is primarily the R(-) enantiomer which causes both the therapeutic ***and adverse beta-adrenergic effects***." [D.I. 264 at 22.] If Dey were correct about this, then by advocating a construction of "side effects" limited to beta-adrenergic effects caused directly by the S(+) isomer, Dey is advocating for a construction of the term "side effects" that ***covers nothing*** (except perhaps teratogenic side effects which Dey never categorizes as either beta-adrenergic or non-beta-adrenergic). Clearly, a construction of a patent term that renders it a nullity, particularly when this term was expressly relied on to secure patentability, would be both illogical and would expose the claims to further invalidity attacks, which, of course, is the real result-driven rationale underlying Dey's construction.

Still further, trying to determine which effects were caused "directly" by the S(+) isomer as opposed to effects caused ***indirectly***, could render these claims vague and indefinite. For example, Dey acknowledges that the S(+) isomer can lead to more side effects in racemic albuterol compared to use of optically pure R(-) isomer by virtue of the fact that S(+) isomer interferes with the efficacy of the R(-) isomer, requiring use of more drug in racemic albuterol. [D.I. 264 at 23-24.] Dey, however, seems to be arguing that this undisputed reduction of "side effects" is not covered by the claim terms because it is somehow caused "indirectly" by the S(+)

isomer. But this argument quickly leads to unsolvable semantic quandaries. If the interference with the efficacy of the R(-) isomer never occurs except in the presence of the S(+) isomer, then why is that effect not caused "directly" by the S(+) isomer? The construction of "side effects" advanced by Dey renders the claims vague and indefinite, whereas Sepracor's construction is clear and compelled by the plain meaning of the claim terms.

Moreover, Dey's undefined term "beta-adrenergic" appears only once in connection with some of the side effects listed in the specification. [Exh. 1, '755 patent Col. 1:57-61, linking tremor, nervousness, shakiness, dizziness, increased appetite, and cardiac arrythmia as being "typically" associated with beta-adrenergic drugs.] Other specifically disclosed side effects, including, "excitement," "nervousness," and "hyperkinesia" are not expressly linked to beta-adrenergic drugs. [Exh. 1, '755 patent Col. 1:61-63.] Is Dey illogically arguing that these specifically disclosed side effects are not covered by Sepracor's claims? It is not clear. And if so, how do we distinguish a beta-adrenergic side effect from a non-beta adrenergic side effect? Dey's construction would require a *Markman* hearing simply to give meaning to its hoped for result of this *Markman* hearing.

In any event, as explained in Sepracor's opening brief, there is no need to open up the Pandora's box of illogical results introduced by Dey's proposed construction. Sepracor's plain construction leads to no such confusion and is mandated by the intrinsic record. Specifically, the inventors taught the undesirable side effects are those that are associated with the racemic mixture (racemic albuterol) ***or*** the therapeutically inactive isomer, i.e., the S(+) isomer, and not just those associated with the S(+) isomer:

> . . . Applicants' disclosure which teaches that undesirable side effects are ***associated with the racemic mixture or*** the therapeutically inactive isomer, i.e., the S(+) isomer, of albuterol,

but not with the R(-) isomer. [Exh. 8, July 14, 1992 Preliminary Amendment, pg. 3, (underline emphasis in original)].

Thus, any reduction of "side effects" that results from use of optically pure R(-) albuterol compared to the side effects associated with racemic albuterol (whether those side effects were caused "directly" by the S(+) isomer, "indirectly" by the S(+) isomer, or by some manner in which the R(-) and S(+) isomer detrimentally interact) is covered by the claims.

B. The Proper Construction Of "Chronic Administration" And "Chronically Administering"[7]

Sepracor's Construction	Dey's Construction
plain meaning – administer the drug to a human on a recurring basis to prevent or reduce the extent to which bronchospasms occur	means prophylactic administration or periodic administration[8]

The dispute regarding the terms "chronic administration" and "chronically administering" is quite simple -- whether "chronic" requires recurring therapy as Sepracor proposes or whether "chronic" can mean a single prophylactic administration as Dey suggests. Dey's construction excludes the requirement that therapy must be ***recurring***. This construction flies in the face of the plain meaning of the term "chronic." [*See*, *for example*, Exh. 19, Webster's Medical Desk Dictionary which defines "chronic" as "a: marked by long duration, by frequent recurrence over a long time, and often by slowly progressing seriousness : not acute …

[7] The terms "chronic administration" and "chronically administering to the individual" appear in Claim 1 of the '755 patent.

[8] Dey originally took the position that the terms "chronic administration" and "chronically administering" are defined in the prosecution history to mean prophylactic treatment. [*See* Exh. 13, Dey's Response to Sepracor Interrogatory No. 1. at 3.] In its opening claim construction brief, Dey takes the position that these terms mean prophylactic administration or periodic administration.

b: suffering from a disease or ailment of long duration or frequent recurrence <~ arthritic> <~ sufferers from asthma>."]

The intrinsic record makes plain that the term "chronic" only makes sense in the context of recurring therapy. In the May 11, 1994 Declaration of T. Scott Johnson, he explains that "chronic" therapy is what prevents asthma from recurring. This clearly indicates that a single, prophylactic administration will not suffice to treat this disease:

> "Since the patient has asthma (i.e. suffers from a disease state), and treatment is to be prophylactic, treatment would have to be chronic. If the treatment were not chronic, cessation of administration might or might not lead to an immediate attack, but it would certainly lead to reestablishment of the disease condition." [Exh. 10, Declaration of T. Scott Johnson, p. 2-3.]

After Dr. Johnson's declaration was submitted to the Patent Office, the Examiner allowed the claims and explained his reasons for allowance:

> "The Examiner agrees with the statements made by both applicants and the declarant that support exists in the present specification for avoidance of the side effects associated with chronic therapy for asthma…. the R(-) isomer of albuterol does not cause the hypersensitivity reaction normally associated with ***long-term racemic albuterol administration*** in patients suffering from asthma." [Exh. 7, Examiner's Amendment/Reasons for Allowance, p. 2-3.]

The Examiner, in allowing the claims, recognized that the hypersensitivity side effect (again, a side effect that neither defendant's construction would cover) was at least one side effect that could be avoided or minimized by administering optically pure levalbuterol on a continuous and recurring basis in place of racemic albuterol to avoid the onset of an asthma attack.

Thus, at a minimum, "chronic" means more than a single administration, and a single prophylactic administration would not be "chronic." Sepracor does not dispute that

"prophylactic" falls within the definition of "chronic" as used in the claims if the prophylactic therapy is also recurring.

Further, Dey is wrong that Dr. Johnson's declaration somehow redefined the plain meaning of "chronic." [D.I. 264 at 25-26.] All Dr. Johnson said is that "chronic" administration is ***"implicit"*** in the specification's discussion of "prophylactic" or "periodic" use. The argument that "chronic" administration is ***"implicitly"*** supported by this portion of the specification is tantamount to an admission that the specification does not ***"expressly"*** disclose, much less define, the term chronic. Dr. Johnson, however, could not have been clearer, as discussed above, that "chronic" administration requires recurring administration.

C. The Proper Construction Of "Inducing Bronchodilation Or Providing Relief Of Bronchospasm"[9]

Sepracor's Construction	Dey's Construction
plain meaning – inducing bronchodilation or providing relief of bronchospasm	means treating asthma

Similar to the claim terms "chronic administration" and "chronically administering," Dey seeks to redefine the plain meaning of the term "inducing bronchodilation or providing relief of bronchospasm" to mean simply treating asthma. Dey's construction ignores the plain language of the claim and instead relies on a statement that Sepracor made in a different patent application about the patent claims in which these disputed terms appear. [D.I. 264 at 33.] Specifically, Dey argues that because Sepracor stated that its '002 patent claims "***relate*** to methods for treating asthma" this somehow redefines the plain and ordinary meaning of the claim term "inducing bronchodilation or providing relief of bronchospasm." This makes no

[9] The term "inducing bronchodilation or providing relief from bronchospasm" appears in Claims 1 and 10 of the '002 patent, and the term "bronchospasm" appears in Claims 1 and 10 of the '993 patent.

sense. Sepracor's '002 patent claims can ***relate*** to treating asthma, and at the same time not be limited to treating asthma. Dey's claim construction argument here is based on impermissibly reading extraneous limitations into the claims.

Notably, the construction Dey advances is at odds with its own stated understanding of the words of this claim term. Dey concedes in its opening brief that "bronchodilation" is a relaxation of the airway smooth muscle, and that "bronchospasm" is breathing difficulty. [D.I. 264 at 28 and 31.]

Sepracor's construction derives from the plain meaning of the claim language, *i.e.*, "inducing bronchodilation" refers to causing an increase in caliber of the bronchi and bronchioles, and "providing relief of bronchospasm" refers to providing relief of contractions of smooth muscle in the walls of the bronchi and bronchioles. [See Exh. 18 at 213-214, which provide supporting definitions for the terms bronchodilation and bronchospasm.] Accordingly, this Court should adopt Sepracor's proposed construction.

D. The Proper Construction Of "Reversible Obstructive Airway Disease"[10]

Sepracor's Construction	Dey's Construction
plain meaning – "reversible obstructive airway disease"	"reversible obstructive airway disease" means asthma

Dey's construction of the term "reversible obstructive airway disease," as is the case with many of its constructions, seeks to redefine the plain language of this claim term. Here, Dey attempts to redefine "reversible obstructive airway disease" to mean asthma. Dey's stated reason for limiting this claim term to asthma is that the patent specification allegedly refers only to methods for treating asthma. [D.I. 264 at 34.] Here again, Dey improperly seeks

[10] The term "reversible obstructive airway disease" appears in Claims 1 and 10 of the '993 patent.

to read limitations from the patent specification into the claims. *Phillips*, 415 F.3d at 1323 (Courts must "avoid the danger of reading limitations from the specification into the claims."). Moreover, the patent specification does not say what Dey suggests. For example, the first sentence of the Summary of Invention section states that the invention relates to "a method of treating ***bronchial disorders***, ***such as*** asthma . . . ." [Exh. 1, '755 patent, Col. 1:41-42.]

In addition, Dey cites to three extrinsic documents in support of its attempt to limit the plain and ordinary meaning of the term "reversible obstructive airway disease." [D.I. 264 at 34.] None of these documents support Dey's construction. As Dey points out, the first document (Exh. 22 to Dey's opening brief) states that asthma is a lung disease having "airway obstruction that is reversible (but not completely in some patients) either spontaneously or with treatment…." This, however, does not provide a definition for the term "reversible obstructive airway disease." In fact, this reference does not even use the term "reversible obstructive airway disease." Instead, it purports to define asthma. The second document Dey cites (Exh. 23 to Dey's opening brief) is an excerpt from product information concerning Proventil® brand racemic albuterol. Without explanation, Dey asserts that this document indicates reversible obstructive airway disease is used interchangeably with asthma. The document, however, makes no such statement or suggestion. It simply states that Proventil is "indicated for the relief of bronchospasm in patients with reversible obstructive airway disease." It does not say that reversible obstructive airway disease is asthma. According to Dey, the third document it cites (Exh. 24 to Dey's opening brief) states that asthma is a disease characterized by "reversible airway obstruction." Putting aside the fact that the claim term at issue is "reversible obstructive airway disease" and not "reversible airway obstruction," Dey misses the point. The issue is what is meant by the term "reversible airway obstructive airway disease" and not what is the definition

of asthma. Further, nothing in Dey's cited document establishes that "reversible obstructive airway disease" means "asthma." If anything, this document supports that "reversible obstructive airway disease" includes many conditions other than asthma, as Sepracor explained in its opening brief. For example, Table 1 of this document, similar to the article on which Sepracor relied in its opening brief, refers to several respiratory conditions under the umbrella of "reversible obstructive airway disease" such as asthma, chronic bronchitis and emphysema. [D.I. 267, Exh. 24 at 1368.]

In contrast to Dey's construction, Sepracor's construction does not ask the Court to redefine the term "reversible obstructive airway disease." Sepracor's construction derives from the plain meaning of the term, *i.e.*, a respiratory disorder such as asthma, chronic bronchitis, and emphysema.

E. The Proper Construction Of "Acute Administration"[11]

Sepracor's Construction	Dey's Construction
plain meaning – administration to treat an acute attack of asthma	treatment after onset of an asthma attack for the purpose of reducing bronchospasm

Dey identified the purported need to construe the term "acute administration" for the first time in its opening claim construction brief. [D.I. 264 at 27.] Sepracor proposes that the Court construe the term acute administration consistent with its plain and ordinary meaning. Specifically, in this context, "acute administration" refers to a one time administration as opposed to chronic administration which requires recurring use.

Dey, on the other hand, seeks to redefine "acute administration" to "treatment after the onset of an asthma attack for the purpose of reducing bronchospasm." Dey's

[11] The term "acute administration" appears in Claims 1 and 5 of the '994 patent.

construction is unsupported by the plain language of the claim. For example, the claim language does not refer to administration "for the purpose of reducing bronchospasm." Instead, the claim language refers simply to acute administration.

Dey attempts to support its construction based on its flawed understanding of the prosecution history of the Sepracor patents. [D.I. 264 at 28.] Specifically, Dey relies on the inventors' statement that "[t]he reference to the administration of albuterol to an individual 'after onset of asthma to reduce breathing difficulty (line 7) reflects acute medication, whereas the reference to prophylactic treatment (line 10) refers to chronic therapy." Contrary to Dey's assertions, the inventors were not redefining the plain meaning of the term "acute administration" with this statement. Instead, they explained where support for their claims could be found in the patent specification.

This Court should reject Dey's attempt to read extraneous limitations into the patent claims.

F. The Proper Construction Of "Preventing Bronchospasm In A Patient With Reversible Obstructive Airway Disease"[12]

Sepracor's Construction	Dey's Construction
plain meaning – preventing bronchospasm in a patient with reversible obstructive airway disease	means chronically treating a patient for asthma

Dey identified the purported need to construe the entire claim phrase "preventing bronchospasm in a patient with reversible obstructive airway disease" for the first time in its opening claim construction brief. [D.I. 264 at 33.] Sepracor proposes that the Court construe this term consistent with its plain and ordinary meaning, *i.e.*, preventing bronchospasms in a

[12] The term "preventing bronchospasm" appears in Claim 10 of the '993 patent.

patient with reversible obstructive airway disease. There is nothing ambiguous regarding this claim term. As explained above, the term "bronchospasm" refers to contraction of smooth muscle in the walls of the bronchi and bronchioles, and the term "reversible obstructive airway disease" is not limited to asthma.

Dey, however, seeks to redefine this plain claim language to mean "chronically treating a patient for asthma." [D.I. 264 at 35.] According to Dey's construction, the term "preventing bronchospasm" is reduced to "chronically treating," and the term "reversible obstructive airway disease" is reduced to "asthma." There simply is no support for rewriting these claim terms as Dey proposes. As it has done with many of the disputed claim terms, Dey argues that Dr. Johnson's declaration, which was submitted long before the claim terms at-issue were presented to the Patent Office, somehow redefines these claim terms. The Court should reject Dey's attempt to read extraneous limitations into the patent claims.

CONCLUSION

For the foregoing reasons, and the reasons set forth in Sepracor's opening claim construction brief, Sepracor respectfully requests that the Court adopt its constructions of the disputed claim terms of the asserted patents

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CERTIFICATE OF SERVICE

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